IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Tsunehiro FUKUCHI et al.:

Serial No. 10/522,603: Art Unit: 1655

Filed: January 26, 2005: Examiner: Catheryne CHEN

For: CHINESE HERBAL MEDICAL COMPOSITION IN THE FORM OF JELLY

DECLARATION

Honorable Commissioner for Patents

Sir:

I, Tsunehiro FUKUCHI, a citizen of Japan residing in A201, East 16, 541, Kirai, Higashikagawa-shi, Kagawa-ken, Japan, declare as follows:

I graduated from Kagawa University, Department of Education in 1991, and graduated Kyushu Institute of Technology, School of Computer Science and System Engineering in 1994.

From 1994 to now, I have been employed in TEIKOKU SEIYAKU CO., LTD. and I have engaged in research and development on the preparation of Chinese medicines in said company.

I am one of inventors of the above patent application (U.S. Serial No. 10/522,603) and am familiar with subject matter thereof.

Under my supervision the following tests were carried out.

The following experiments were carried out experiments to confirm whether or not the preparation containing a Chinese herbal medicine according to Fukui et al. (U.S. Patent 6,277,395 B1) is

for long term preservation.

1. Samples for tests

A manufacturing method of samples:

Each ingredient shown in the following Tables was weighed, and the ingredients were homogenously mixed and stirred, followed by addition of water. The mixture was stirred and dissolved under heating at 80°C for 1 hour. The solution was instantly poured into a stick-like vessel and then was left at 20 to 25°C for more than 12 hours to solidify.

Sample A: having the same ingredients as example 2 of the present invention.

Samples a, b and c: being prepared by mixing Chinese herbal medicine, Kakkonto to ingredients of Embodiment 1 of Fukui et al.

Table 1

	Sample a	Sample b	Sample c
Aqueous dry extract of Kakkon-to (葛根湯)	30.00	15.00	15.00
Agar	0.20	0.20	0.20
Locust bean gum	0.05	0.05	0.05
Pectin	0.04	0.04	0.04
Carrageenan (ι)	0.02	0.02	-
Carrageenan (κ)	-	-	0.02
Xanthangum	0.01	0.01	0.01
Citric acid	0.21	0.21	0.21
Trisodium citrate	0.14	0.14	0.14
Erythritol	8.82	8.82	8.82
Flavor	-	-	-
Purified water	60.51	75.51	75.51
Total	100.00	100.00	100.00

Table 2

	Sample A
Aqueous dry extract of Kakkon-to (葛根湯)	15
Carrageenan (ι)	1
Locust bean gum (Carob bean gum)	0.25
Xanthangum	0.45
Powdered hydrogenated maltose starch syrup	6
D-Sorbitol	6
Glycerin	6
Propylene glycol	1
Propyl parahydroxybenzoate	0.02
Purified water	64.28
Total	100.00

2. Stability Test

(1) Syneresis

The preparation kept at 25°C 60%RH and by standing on end of the stick-like vessel containing a sample was used for this test.

After previously weighted the weight of metal gauze with mesh size of 355μm and the weight of soft paper for absorbing water separated from the sample, the paper folded up was put under the metal gauze. The stick-like vessel was opened and its content (sample) was put on the metal gauze.

Separated water was absorbed with the paper under the metal gauze taking 1 minute. The weights of the metal gauze with the sample and the paper containing the separated water were measured. Amount (%) of separated water (syneresis) was calculated from the above measured weights.

The results are shown in Table 3.

Observation

The preparation of Sample A of the present invention hardly shows syneresis. On the other hand, syneresis on Samples a, b and c of Fukui et al. were very great and these Samples can not be used for long term preservation.

Table 3

25℃ 60%RH	Initial value*	After 10 days	After 67 days
Sample a	3.82 ±(2.33)%	25.20 ±(0.28)%	37.86 ±(7.33)%
Sample b	35.22 ±(2.26)%	35.91 ±(3.26)%	31.37 ±(5.88)%
Sample c	18.28 ±(0.70)%	21.90 ±(0.93)%	29.03 ±(2.75)%
Sample A	0.02 ±(0.02)%	0.04 ±(0.03)%	0.17 ±(0.08)%

* One day after manufacturing the sample, the value which was measured on the sample was as initial value.

The results shown in Table 3 are also shown in following figures (Fig. 1 to 2).

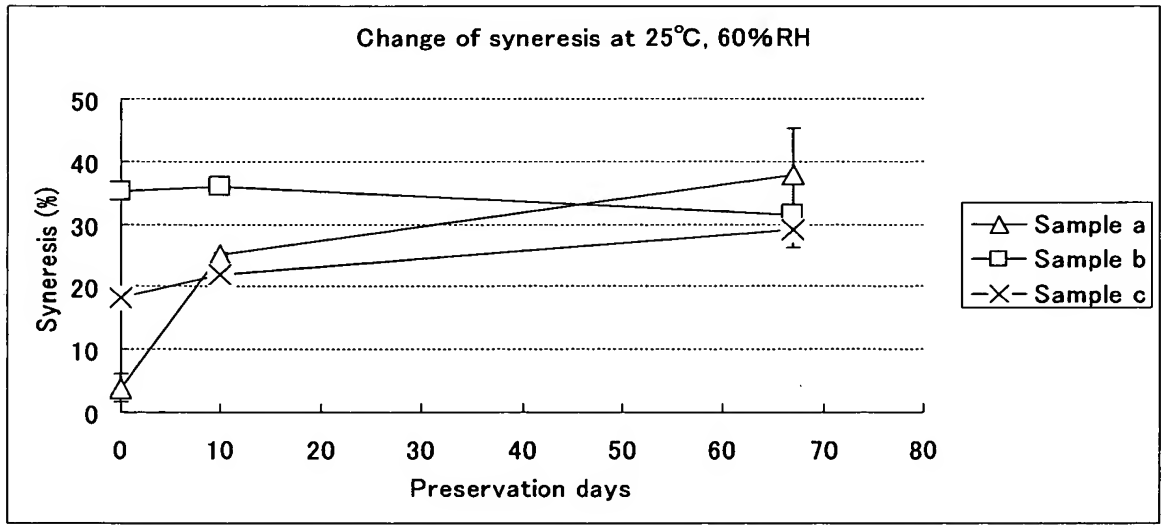


Fig. 1

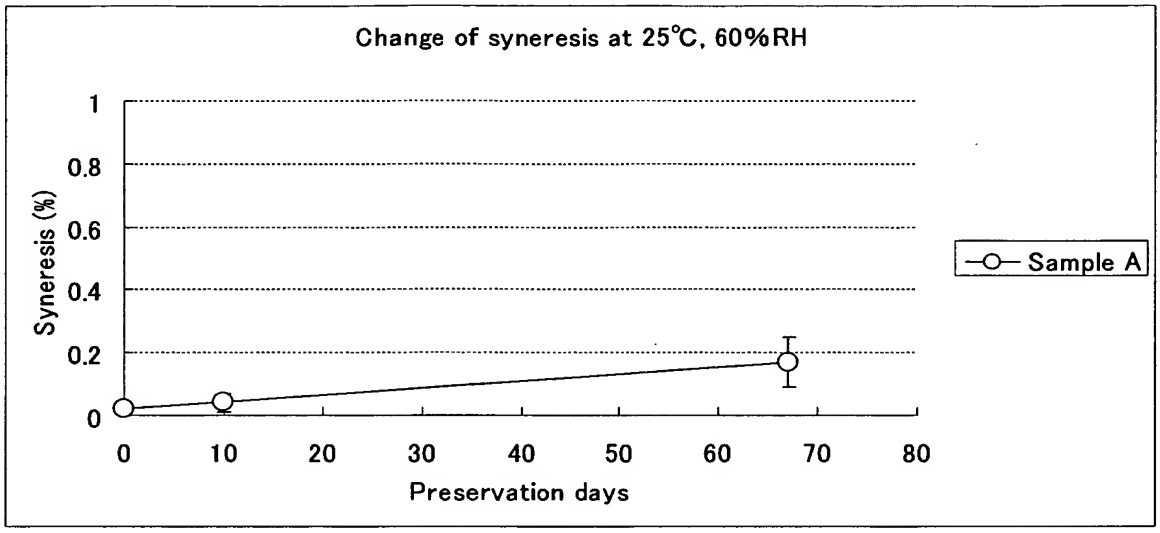


Fig. 2

(2) Change of breaking load (strength of gel)

The test was carried out using an equipment shown in attachment.

Equipment for measurement: Creep meter (Yamaden Co.)

After putting a Sample into a plastic Petri dish (Diameter: 51mm, Height: 9mm), the dish was covered with a lid and covered around the dish with parafilm (Laboratory film: ALCAN) for protecting spatter of the water and then the test was carried out.

Samples which had kept at 40°C 75%RH and 25°C 60%RH were take out and said samples were kept at 20±3°C for about 6 to 12 hours for preconditioning, the test on the samples was carried out under the following condition.

Plunger diameter: 1cm, height: 3cm, compression speed: 1mm/sec

Clearance 45%, measured temperature: 20±3°C

The maximum breaking load was measured as strength.

The results were shown in following Tables 4 and 5.

Table 4

25℃ 60%RH	Initial value *		After 5 days		After 10 days	
Sample a	3.40	±(1.18) gf	4.42	±(0.59) gf	4.76	±(0.59) gf
Sample b	4.76	±(2.57) gf	2.72	±(0.59) gf	3.40	±(0.59) gf
Sample c	6.46	±(0.59) gf	6.12	±(0.00) gf	6.12	±(0.00) gf
Sample A	208.02	±(5.40) gf	196.13	±(14.29) gf	180.15	±(36.50) gf

Table 5

40℃ 75%RH	Initial value *		After 5 days		After 10 days	
Sample a	3.40	±(1.18) gf	5.78	±(0.59) gf	5.44	±(0.59) gf
Sample b	4.76	±(2.57) gf	3.06	±(0.00) gf	2.04	±(0.00) gf
Sample c	6.46	±(0.59) gf	6.12	±(0.00) gf	5.10	±(0.00) gf
Sample A	208.02	±(5.40) gf	234.88	±(26.68) gf	200.20	±(5.62) gf

* One day after manufacturing the sample, the value which was measured on the sample was as initial value.

The above results are also shown in Fig. 3 to 6.

Observation

Gel strength on every sample was hardly changed for preservation for long term.

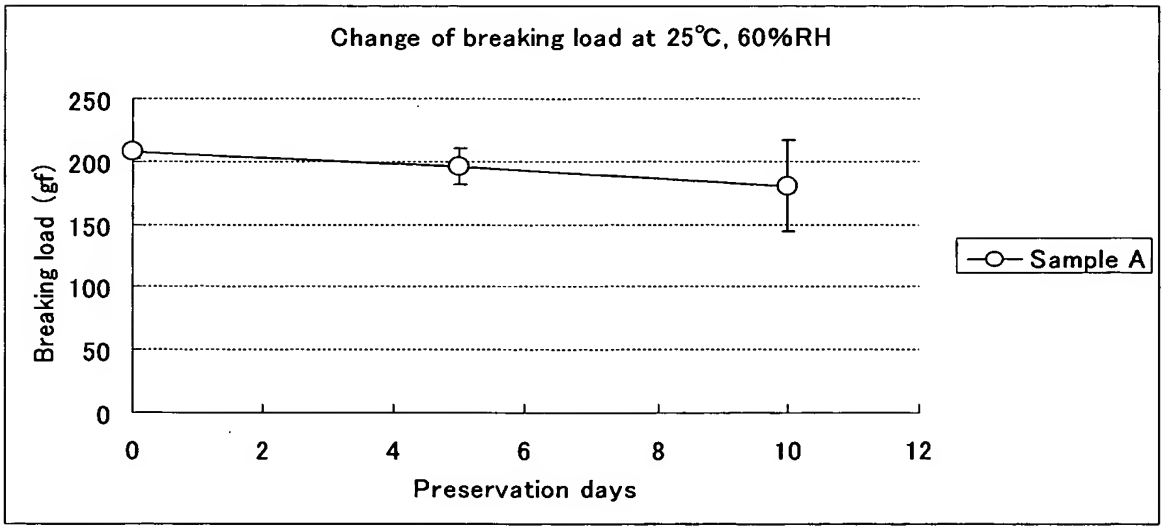


Fig. 3

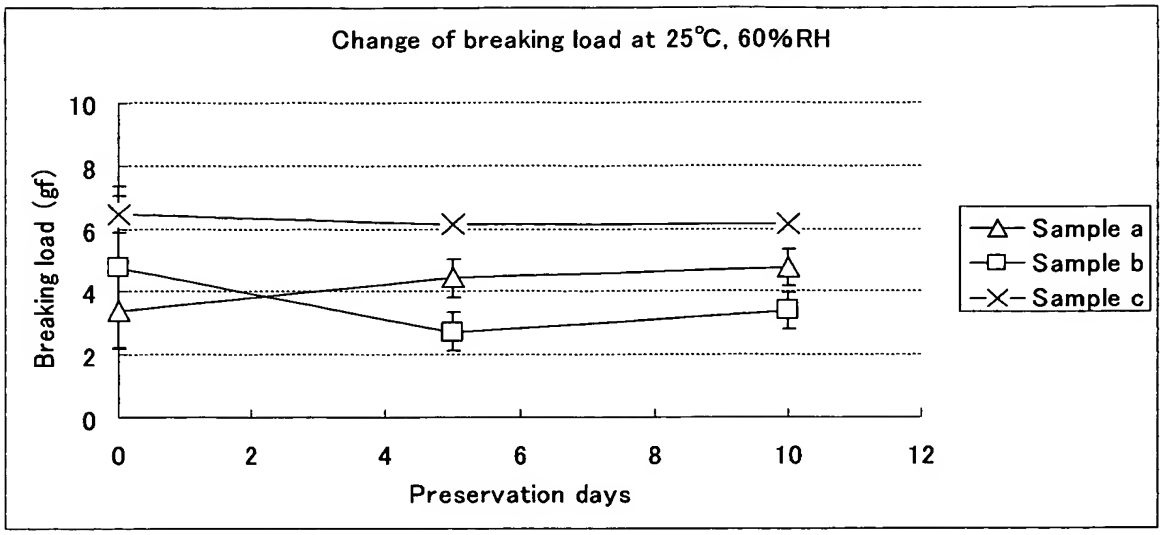

Change of breaking load at 25℃, 60%RH
Breaking load (gf)
10
8
6
4
2
0
0
2
4
6
8
10
12
Preservation days
Sample a
Sample b
Sample c

Fig. 4

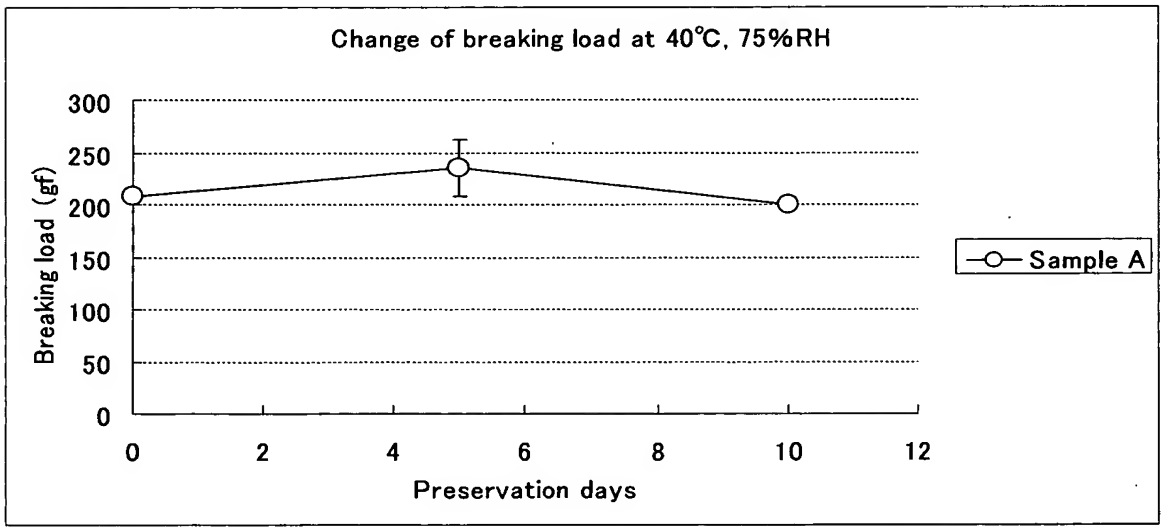

Change of breaking load at 40℃, 75%RH
Breaking load (gf)
300
250
200
150
100
50
0
0
2
4
6
8
10
12
Preservation days
Sample A

Fig. 5

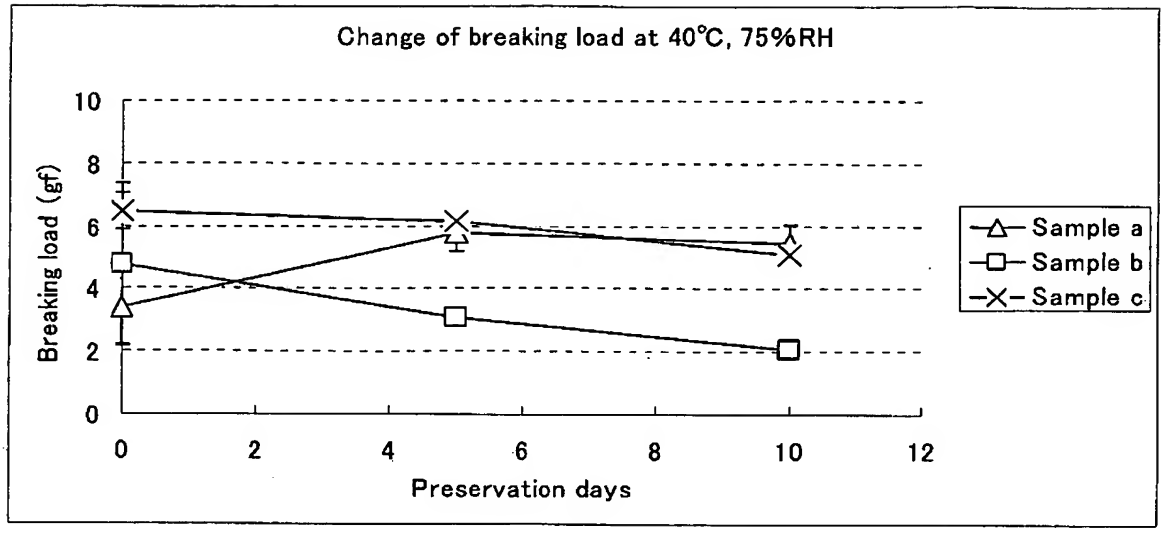


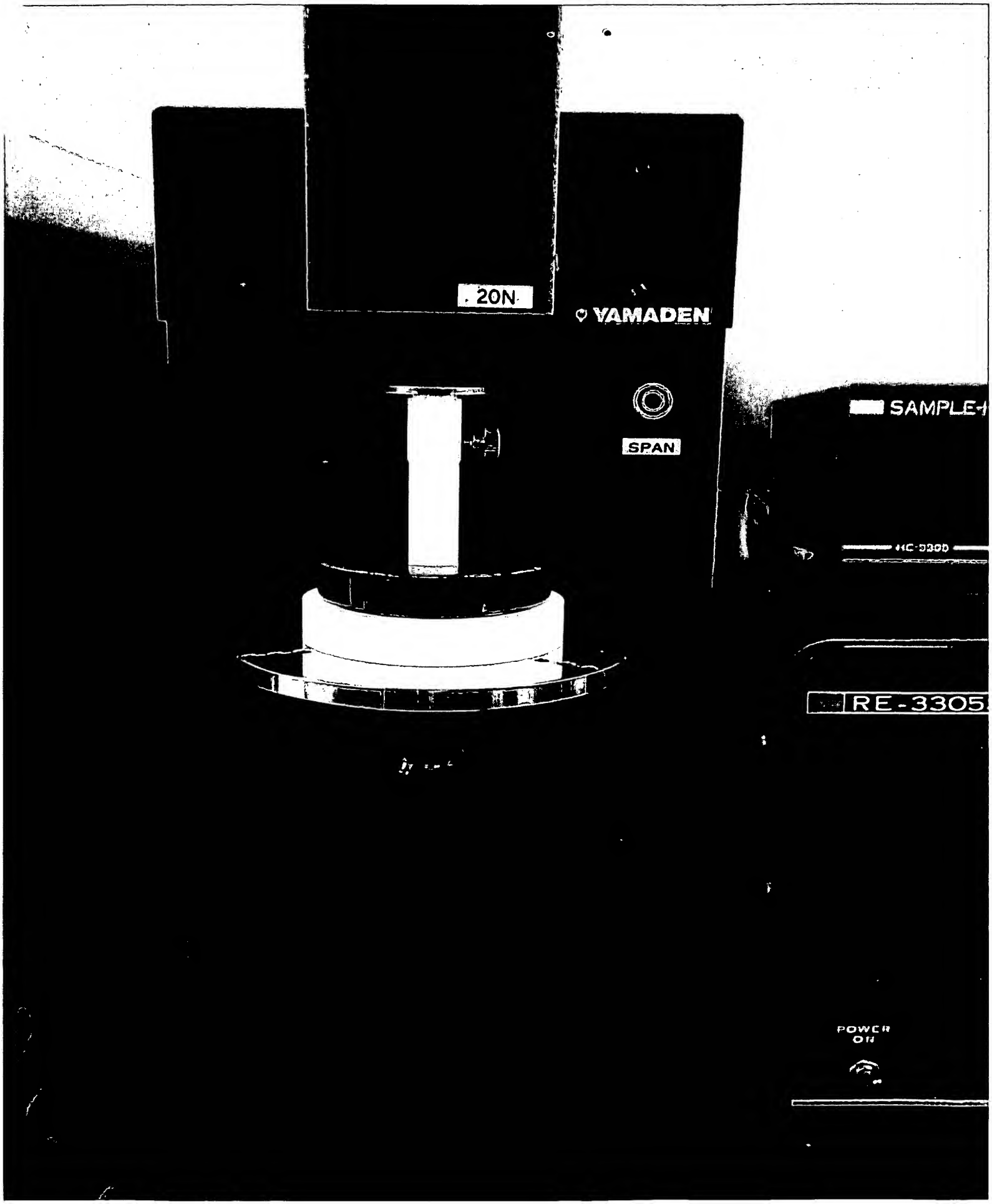
Fig. 6

The undersigned declares further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United State Code and that such willful false statements may jeopardize the validity of the above-mentioned application or any patenting thereon.

This 7 of December, 2007

Tsunehiro Fukuchi

Tsunehiro FUKUCHI


20N
YAMADEN
SPAN
SAMPLE-I
HC-5300
RE-3305
POWER
ON